

SUBMISSION READINESS

SA05

Ali Dootson



ALI DOOTSON

VISION, PROBLEM SOLVING & THOUGHT LEADERSHIP



ALI DOOTSON

Top 5 Strengths:

*Ideation, Significance
Self-Assurance, Adaptability,
Learner*

EXPERIENCE SUMMARY

A visionary leader who brings a deep understanding across a broad portfolio of global pharmaceutical R&D, Data Management, Biometrics, Regulatory, Quality and IT disciplines. More than 25-years of direct pharmaceutical business and IT experience in sponsor, CRO and consulting organizations with a track record of developing business opportunities, nurturing leads and closing sales with strategic customers and thus achieving business value and efficiencies through business process optimization, system deployments/integrations, and management of technologies. Ali is committed to learning to aid in successfully leading engagements; engages in creative problem solving, is entrepreneurial and collaborative.

RELEVANT EXPERIENCE

Ali's work includes the following:

- Leads the analysis and formulation of R&D strategic planning and future state recommendations for analytic capabilities across small-to-large global sponsors and CROs.
- Leads the analysis, design, and delivery of numerous global analytic platforms which provided data processing and analytical capabilities to R&D, Epidemiology, and Commercial business units.
- Partnered, engaged, and/or delivered projects with 70% of the top 10-pharmaceutical companies (45% of the top 40) and over 50 different organizations.
- Driving industry engagement, including contributing, speaking and volunteering for phuse
- Built strong relationships with a wide range of clients
- Defined value propositions and sales kits to assist with sales leads
- Developed and provided leadership to engaged teams
- Established a high performing, engaged team

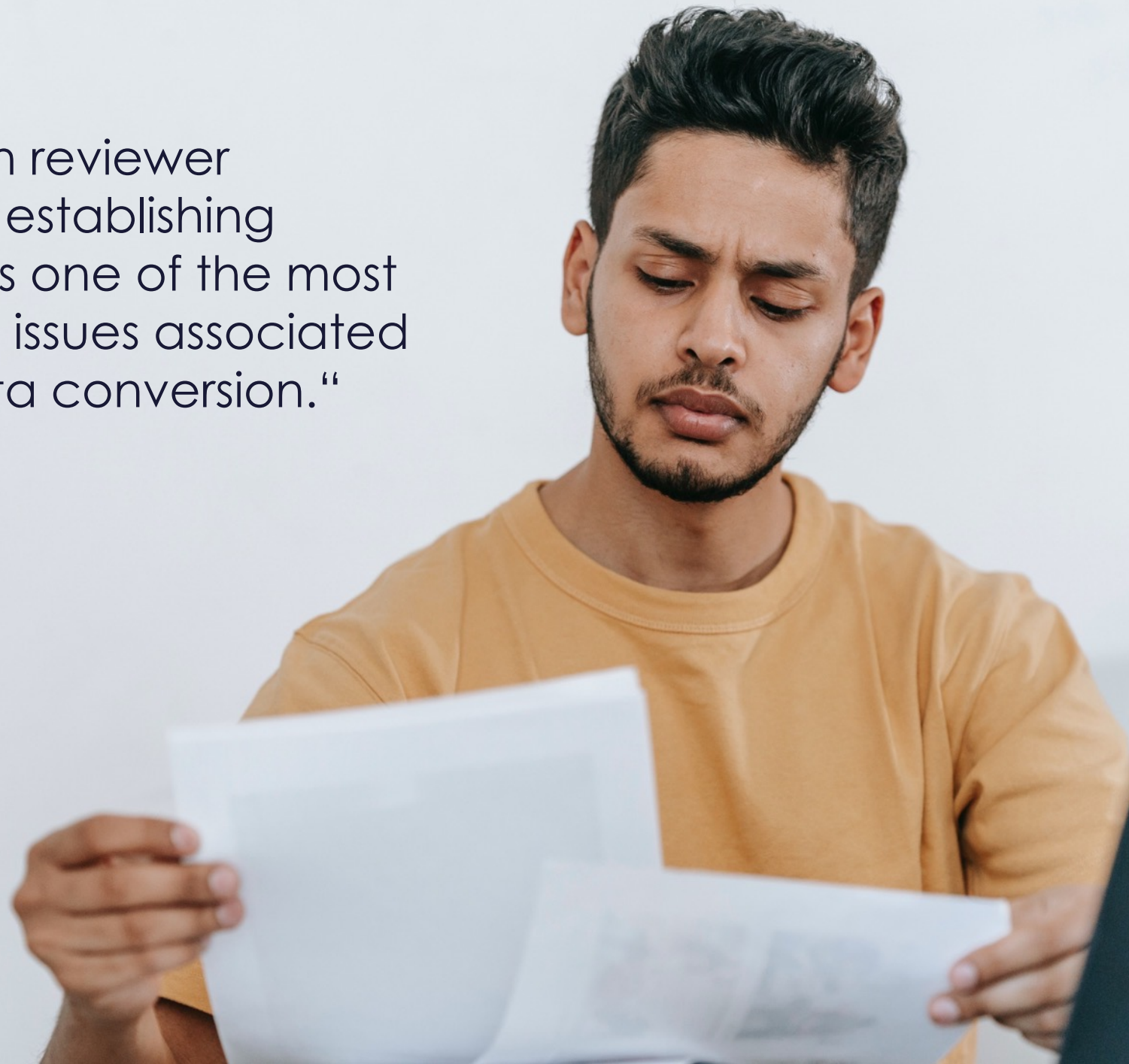
EDUCATION & CERTIFICATIONS

- Master of Science (MS), Global Management
- Bachelor of Science (BSc), Management Science
- High Ticket Closer



SUBMISSION
REJECTED!

“Based upon reviewer experience, establishing traceability is one of the most problematic issues associated with any data conversion.”



DAY IN THE LIFE...

THE STATE OF MY CLINICAL DATA?

- » What is the significance of December 17th 2014/2016?
- » In 2018, according to FDA, approximately 30% of marketing applications received had critical data compliance errors
- » CDER and CBER began rejecting submissions that fail eCTD study data validations on September 15, 2021
- » Have we received feedback from FDA on our study data standardization plan for our upcoming submission?



« We acquired our compound from another company, what should I do with the legacy data?

« Are the clinical data assets & artifacts that we possess as an organization aligned with current regulatory guidance?

« How confident are we as an organization that our greatest asset, our 'data' is ready for our upcoming submission?

WHO IS THIS FOR



EMERGING BIOTECH (I.E. SMALL BIOTECH)

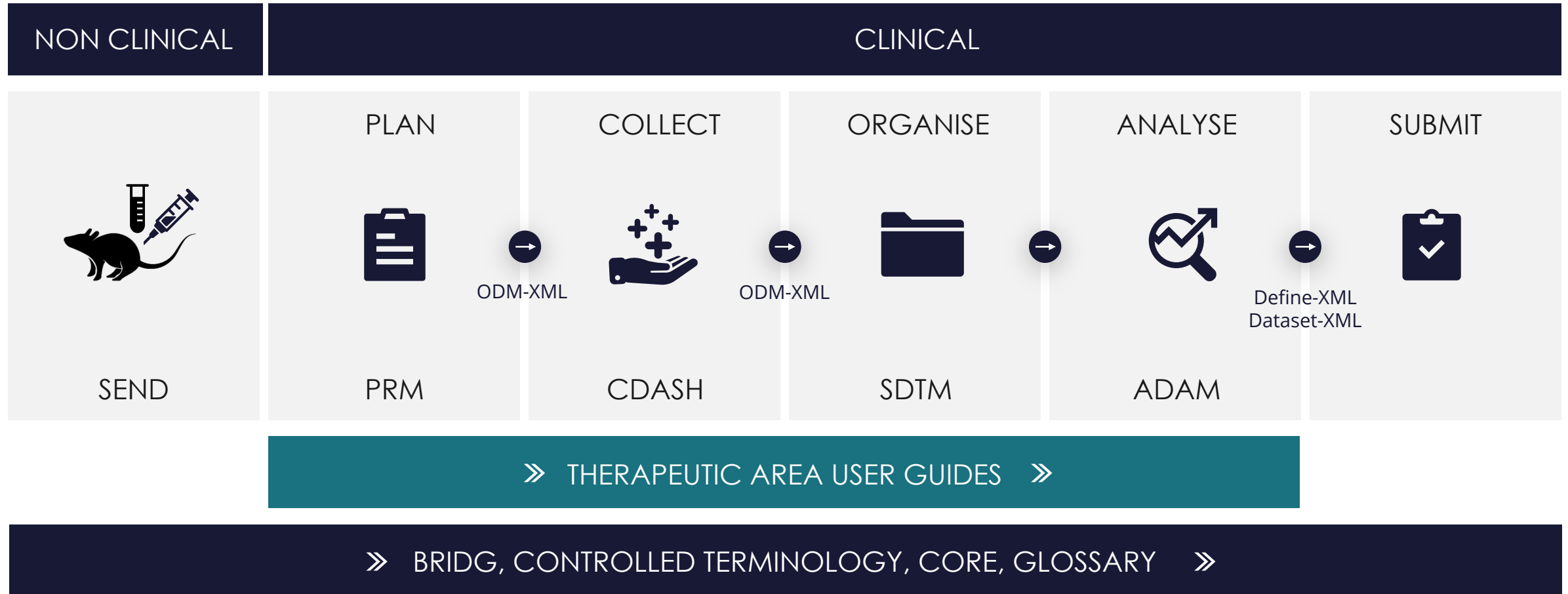
- » Are you planning an upcoming marketing application/submission (preparing for Pre-NDA meeting, end of phase II etc.)?
- » Have you acquired another compound and are further researching the compound for eventual marketing purposes?
- » Do you outsource significant amount of clinical operations work?
- » Are you the parent company of small biotech(s)?



LARGE PHARMA

- » Typically, this function or expertise exists within large pharma, however regulatory function is sometimes misaligned with the clinical team specific to data standards and FDA guidance
- » Are you working with legacy data?

USE OF CDISC STANDARDS



STUDY DATA TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

This Document is incorporated by reference into the following
Guidance Document(s):

Guidance for Industry Providing Regulatory Submissions in Electronic Format – Standardized Study Data

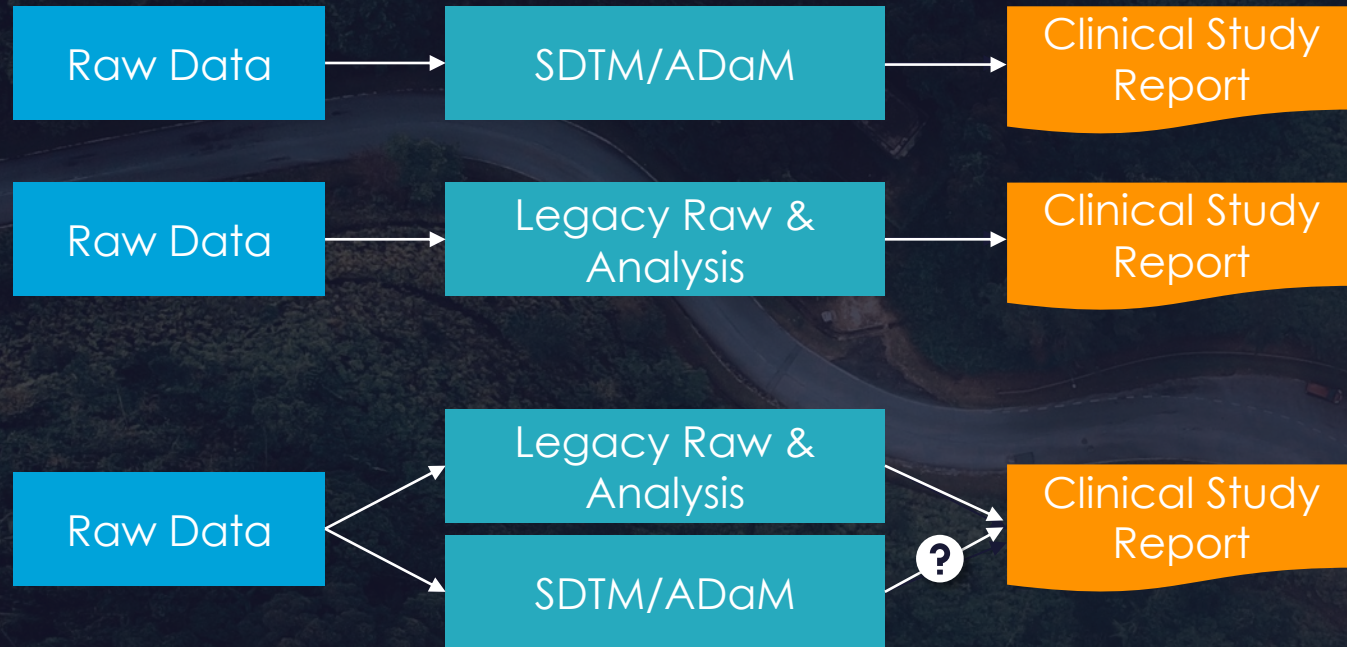
For questions regarding this technical specifications document, contact CDER at
cdcr-edata@fda.hhs.gov or CBER at cber-edata@fda.hhs.gov

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

March 2022

<https://www.fda.gov/media/153632/download>

PATHS TO TRACEABILITY



Is there an established path of traceability for each study?

Does the established path of traceability meet current FDA expectations?

What are the current FDA expectations for data standards?

SUBMISSION STRATEGY SCENARIOS



Upcoming NDA/BLA



- Some studies contain CDISC data packages from a tabulation and analysis perspective
- Some studies did not use CDISC data inputs to produce tables, listings, and figures in the report



- Determine which data are essential to submit supporting traceability
- Engage with FDA directly to align on expectations



Integration of Data



- Numerous studies not in CDISC format
- Numerous studies in acceptable versions of SDTM
- Many studies outsourced to various CRO partners



- Determine strategy for integrating data to support integrated summaries
- Identify inconsistent representation of analysis parameters



Compound Acquisition & Partnerships



- Numerous studies in legacy data format
- Dictionary coding information not in some studies
- Programs and reference data used to produce tables, listings, and figures not present



- Conduct detailed review of clinical data assets and compare to current acceptable guidance
- Plan for dictionary coding activities to support integration

FDA DATA STANDARDS CATALOG

FDA Data Standards Catalog v8.2 (08-01-2022) - Supported and Required Standards												
For full description of column headings, see Instr. & Column Descriptions tab												
Use	Data Exchange Standard	Exchange Format	Standards Development Organization (SDO)	Supported Version	Supported Implementation Guide Version	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY) [10] [11]	Date Requirement Ends (MM/DD/YYYY)	Statutory, Regulatory, or Guidance Authority	
Clinical study datasets	SDTM	XPT	CDISC	1.2	Version 3.1.2 Amendment 1	CDER, CBER	08/07/2013	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]	Standardized Study Data	
Clinical study datasets	SDTM	XPT	CDISC	1.3	3.1.3	CDER, CBER	12/01/2012	03/15/2021	12/17/2016 [1] 12/17/2017 [2]	03/15/2021	Standardized Study Data	
Clinical study datasets	SDTM	XPT	CDISC	1.4	3.2	CDER, CBER	08/17/2015		03/15/2018 [1] 03/15/2019 [2]		Standardized Study Data	
Clinical study datasets	SDTM	XPT	CDISC	1.7	3.3	CDER, CBER	03/15/2021		03/15/2023		Standardized Study Data	
Animal Rule study datasets	SDTM	XPT	CDISC	1.8	SENDIG-AR v1.0	CDER	03/15/2020		3/15/2022 [1] 3/15/2023 [2]		Standardized Study Data	
Clinical study datasets	ADaM	XPT	CDISC	2.1	1	CDER, CBER	Ongoing	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]	Standardized Study Data	
Clinical study datasets	ADaM	XPT	CDISC	2.1	1.1	CDER, CBER	03/15/2018		03/15/2019 [1] 03/15/2020 [2]		Standardized Study Data	
Clinical study datasets	ADaM	XPT	CDISC	2.1	1.2, 1.3	CDER, CBER	07/18/2022		03/15/2024		Standardized Study Data	

<https://www.fda.gov/media/160564/download>

SUBMISSION READINESS REVIEW

SUBMISSION READINESS REVIEW

PLAN

- Focus on intended use of your clinical data
- Gain full understanding of the clinical studies to support your compound
- Identify role of each study in upcoming submission
- Establish integrated analyses planning
- Initiate Study Data Standardization Plan
- Set Pre-NDA/BLA Meeting

ASSESS

- Assess clinical data assets available for each study comparing to agency requirements
- Assess traceability as it originates from source data through to clinical study reports
- Define current study timelines, ongoing analyses, expectations
- Obtain agency feedback

RECOMMENDATION

- Produce implementation plan and remediation activities
- Assist with strategic planning and authoring of documentation
- Focus primarily on ensuring sponsor data is compliant prior to agency review



COMMUNICATION



DUE DILIGENCE



SUBMISSION READINESS

EMA RAW DATA ANALYSIS



<https://www.ema.europa.eu/en/news/ema-launches-pilot-project-analysis-raw-data-clinical-trials>

News 12/07/2022

EMA has launched a pilot project to assess whether the analysis of 'raw data' from clinical trials by Regulatory authorities improves the evaluation of marketing authorization applications (MAAs) for new medicines as Well as post-authorization applications and to explore the practical aspect of submission and analysis of such data.

BENEFITS AND VALUE OF REVIEWING YOUR SUBMISSION READINESS



Develop a cohesive Data Submission Strategy – take an end in mind approach based on current regulatory guidance



Create a roadmap for submission readiness – make an individualised assessment of each data asset

Define a remediation plan for each clinical & non-clinical data asset to support submission readiness



Verified Data Integrity & Confidence – by demonstrating traceability

Verification of the lifecycle of your data from collection through to analysis aligns with FDAs expectations



Develop trust within your organisation

Make your stakeholders feel comfortable about the submission



The future transformed for the benefit of everyone.

Intelligent solutions empowering collaboration
and life-enhancing science.



Thank You!

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